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Attached is the 2020-2021 Annual Report for the Committee for Protection of Human Subjects (CPHS). CPHS and the Office for Protection of Human Subjects (OPHS) strive to offer excellent customer service while ensuring the health, welfare and safety of subjects and supporting institutional regulatory compliance.

Please contact us with any questions or comments regarding this report:

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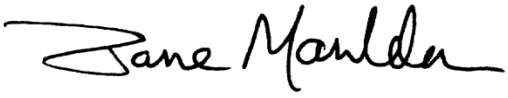
Respectfully Submitted,

William J. Jagust, M.D.

Chair, Committee for Protection of Human Subjects (CPHS-1)
Professor, School of Public Health and Helen Wills Neuroscience Institute



Jane Mauldon, Ph.D.
Chair, Committee for Protection of Human Subjects (CPHS-2)
Associate Professor, Goldman School of Public Policy

Enc. CPHS Membership Roster 2020-2021

Cc: Kairi Williams, Assistant Vice Chancellor for Research Administration and Compliance
Rebecca Armstrong, Director, Research Subject Protection

Report to the Research Compliance Advisory Committee

I. Committee Title and Report Period

Committee for Protection of Human Subjects - Report for July 1, 2020 - June 30, 2021.

II. Executive Summary

From July 1, 2020 - June 30, 2021, the Office for Protection of Human Subjects (OPHS) and the Committee for Protection of Human Subjects (CPHS) reviewed and approved 1684 applications, similar to the number approved during the prior fiscal year. The number of approvals for new protocols was down slightly, amendment approvals were up, and continuing reviews decreased compared to last year.

Noncompliance submissions decreased, official determinations of "not human subjects research" (NHSR) also decreased, as did the number of withdrawn applications, compared to last year. Overall, OPHS review turnaround times remained relatively steady in comparison to last year, with exempt and expedited turnaround times up slightly, and full board turnaround times down slightly (see tables 4 and 5). UC Berkeley's human subjects research portfolio remains primarily social-behaviorally focused at 75% of total approved submissions. Of the 1684 applications approved, 27% of them were federally-funded.

When the revised DHHS regulations governing human subjects research (45 CFR 46), went into effect on January 21, 2019, they expanded exempt categories, included new requirements for informed consent, and did away with the annual review requirement for minimal risk research. These changes allowed more research to be reviewed at the exempt level and expanded the number of protocols eligible to receive a ten year approval period, resulting in a reduced number of continuing review applications over the last fiscal year.

UC Berkeley (UCB) continues to take advantage of flexibility afforded by the regulations in terms of non-federally funded/regulated research. In late 2015, UCB was the first UC System institution to roll out an exempt category #7. This new category permitted minimal risk, non-federally funded or regulated research studies, which formerly had to be reviewed under expedited level review processes, to now be reviewed under exempt level processes. With the implementation of the revised Common Rule on January 21, 2019, many of the studies that would have qualified for review under exempt category #7 now qualify under one or more of the revised federal exempt categories. However, there are still circumstances in which a study will not qualify for exempt review under the federal categories but will qualify under the UCB-specific category. Because the revised Common Rule included a new exempt category #7, CPHS renamed the UCB-specific category to category #70.

During the last fiscal year, OPHS further expanded exempt category #70 to include secondary analysis of private, identifiable data, which previously would have required expedited review. This category continues to benefit researchers in various ways, from filling out a shorter application form to reducing review times. During the 2020-2021 fiscal year, OPHS made 54 new category #70 determinations, saving time for both OPHS staff and for investigators.

The last fiscal year introduced a number of changes due to the COVID-19 public health crisis. OPHS staff worked remotely 100% during the last year, and CPHS full committee meetings were held by Zoom. On 3/20/20, investigators were notified that they must cease all non-essential in-person research immediately. Where possible, investigators were encouraged to use remote forms of data collection, such as conducting interviews by Zoom. Research that could be conducted remotely (e.g., online, via Zoom, via phone, etc.) was able to continue without disruption. Non-essential, in-person research was phased back in during the course of the 2020-2021 fiscal year, through a series of required steps.

Researchers wishing to resume in-person research were required to submit a Human Subjects Research Resumption Proposal to CPHS, as well as a laboratory density proposal or an off-campus research request to the Vice Chancellor for Research Office. OPHS Staff, the CPHS-1 Chair, and VCRO staff worked together to update these forms/processes for each research resumption phase as the COVID-19 public health crisis evolved. See https://cphs.berkeley.edu/covid-19.html and https://vcresearch.berkeley.edu/covid19/research-operations for more information. OPHS staff continued to handle their usual workloads and responsibilities while working from home, along with added pressure to perform rush reviews of COVID-19-related studies. Between 7/1/20 and 6/30/21, OPHS reviewed and approved 76 on-campus research resumption requests and 88 off-campus research resumption requests.

OPHS Staff updates: Beginning on June 1, 2021, staff member Brenda Belcher started a reduced schedule at 80% time, and former OPHS Staff Member, Alexis Clasca, was rehired on a temporary, 6-month basis at 25% time.

III. Committee Membership and Number of Meetings During the Report Period

The Committee is comprised of two panels, CPHS-1 and CPHS-2. While CPHS-1 tends to review more biomedical research and CPHS-2 reviews more social-behavioral research, both committees may review either type of research. During the '20-'21 fiscal year, CPHS-1 convened 10 times and CPHS-2 convened five times. CPHS-1 had 14 regular members and CPHS-2 had 16 regular members (the 2020-2021 CPHS Membership List is attached).

Professor Bill Jagust, MD served as CPHS-1 Chair and Professor Jane Mauldon served as CPHS-2 Chair. Professor Ndola Prata, MD served as CPHS-1 Vice Chair and Professor Oliver John served as CPHS-2 Vice Chair. OPHS staff are authorized as alternate members for OPHS Director Rebecca Armstrong in order to complete IRB review and approval duties, as determined appropriate based on their experience and role in OPHS. Assistant Director Adrienne Tanner served as Dr. Armstrong's alternate at CPHS meetings, as needed.

IV. Summary of Research Protocols Reviewed

Approvals

The total number of human subjects research approval activities for CPHS and OPHS was down slightly at 1684 approvals in comparison to 1695 last year. New protocol approvals were down slightly in comparison to last year, with an increase in exempt determinations and a decrease in new expedited and full board approvals. Exempt amendments were up, expedited amendments were up, and full board amendments were down. Expedited continuing review applications were down, and full board continuing review applications were also down slightly.

Figure 1 shows the total number of applications approved over the last five years. Table 1 breaks down the applications approved over the same period of time based on the type of submission and level of review. These data exclude cases of potential noncompliance, adverse events, unanticipated problems, administrative actions, and withdrawn submissions, which are discussed later in this document.

Figure 1. Total applications approved over 5 years

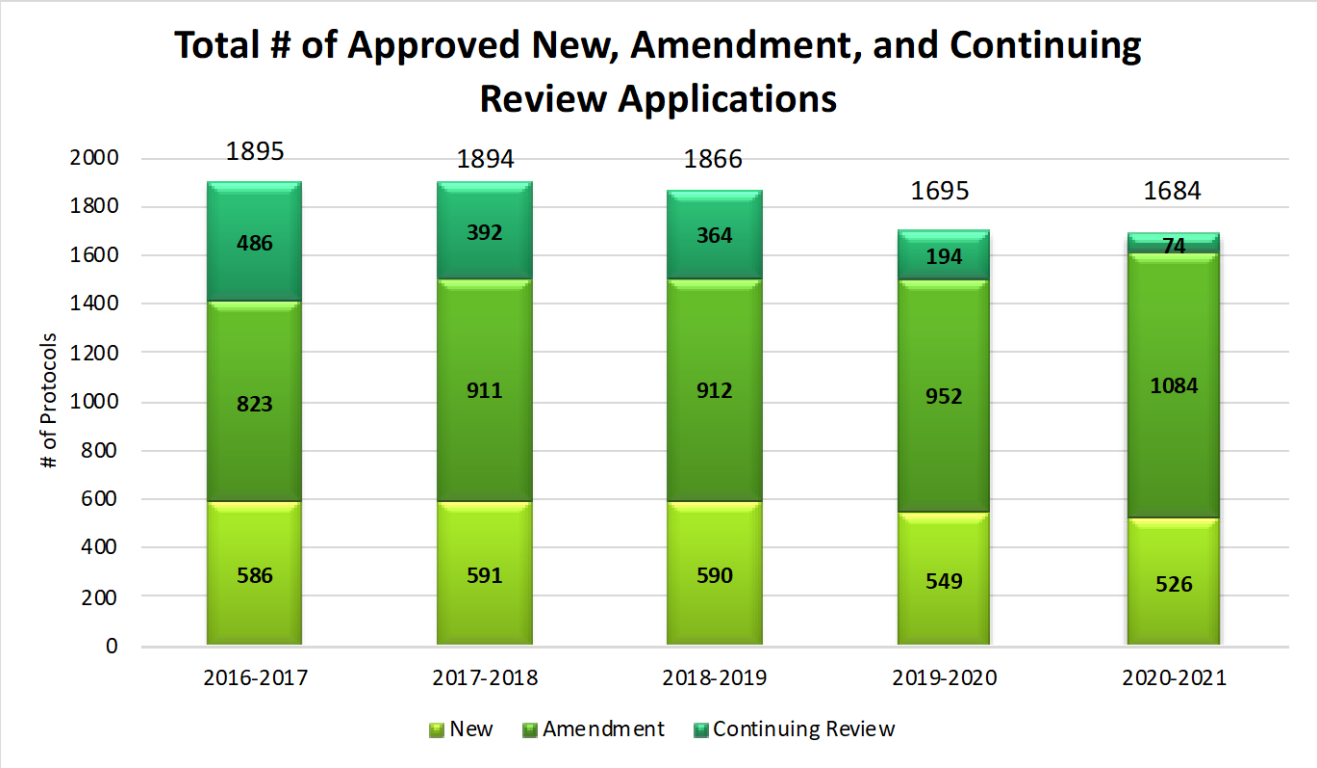


TABLE 1. Types of applications approved over 5 years

Application Type	Review Level	2016-17	2017-18	2018-19	2019-20	2020-21
New	Exempt:	244	224	258	265	298
	Expedited:	287	305	260	235	197
	Full Board:	55	62	72	49	35
	TOTAL	**586**	**591**	**590**	**549**	**526**
Amendment	Exempt:	131	137	162	192	211
	Expedited:	679	759	737	752	868
	Full Board:	13	15	13	8	5
	TOTAL	**823**	**911**	**912**	**952**	**1084**
Continuing Review	Expedited:	453	356	339	168	53
	Full Board:	33	36	25	26	21
	TOTAL	**486**	**392**	**364**	**194**	**74**
Total Activity		**1895**	**1894**	**1866**	**1695**	**1684**

Withdrawn applications
There are times when applications received by CPHS/OPHS are reviewed and then later withdrawn from consideration by the researchers before final approval. The majority of these are new applications, but also include amendments, continuing reviews, and deviation submissions. Table 2 shows applications withdrawn over the last five years by level of review. Out of the 136 applications that were withdrawn this year, 67 were exempt applications, 57 were expedited applications, and 12 were full board applications.

TABLE 2. Applications withdrawn by level of review

Reporting Period	2016-2017	2017-2018	2018-2019	2019-2020	2020-2021
Exempt	62	88	84	80	67
Expedited	82	101	97	90	57
Full Board	9	9	5	11	12
Total:	*153*	*198*	*186*	*181*	*136*

Adverse Events and Unanticipated Problems
There were five incidents reported in the last year. The majority of reports were not unanticipated problems involving risks to subjects. Of the reports that were directly related to the research, steps were taken to prevent similar incidents from happening in the future. One of the reports was an adverse event directly related to the research, the severity of which was unexpected. In that case, the subject was reimbursed for health care costs.

Noncompliances
Whenever a study deviates from the approved protocol, or when activities occur outside of an approval, this is deemed a noncompliance and must be reported to CPHS. Most often these are found to be cases of simple noncompliance, such as exceeding the approved total number of subjects. Twenty-five cases of potential noncompliance were reviewed in the last year, none of which were found to be a serious or continuing noncompliance.

TABLE 3. Noncompliance

Reporting Period	2016-2017	2017-2018	2018-2019	2019-2020	2020-2021
Noncompliance cases	62	79	62	43	25

Subject complaints
OPHS received fifteen subject complaints this past year, most of which involved payment for participation and were quickly resolved by the Principal Investigator. However, three dealt with what the complainant described and viewed as unethical research or research practices, even though they had been evaluated and approved by CPHS.

Administrative actions
OPHS provides consultation on whether an activity is or is "not human subjects research" (NHSR). At times a journal or sponsor may require an official determination of NHSR. OPHS issued 6 official NHSR determination letters last year. Many more determinations were issued informally by email through ophs@berkeley.edu.

If a protocol is submitted through eProtocol that is *not* found to meet the threshold definition of human subjects research, OPHS makes a NHSR determination. Last year, 26 determinations were made in eProtocol. The eProtocol system provides a NHSR determination action notification for researchers as proof of determination.

IRB Reliances

OPHS also processes requests for an institution to rely on the IRB review of another. The process helps prevent duplicative IRB reviews of collaborative projects that involve more than one institution. Investigators can make use of the UC System Memorandum of Understanding (MOU) that permits one campus to rely on the IRB review of another. Outside of the UC system, investigators may request that UCB serve as the IRB of record for a collaborating institution or vice versa. These requests must be reviewed and approved by the OPHS Director. For non-UC collaborations, institutions may enter into Inter-Institutional IRB Authorization Agreements (IIAs), either formally documented with an IIA form or listed on a spreadsheet, depending on protocol specifics.

In addition, UCB is part of the group known as SMART IRB, a mechanism by which multiple IRBs can rely on one IRB, known as an sIRB (single IRB). The development of this group, and the associated software and processes, has been driven by NIH's requirement of sIRB review for multisite, clinical trials. To date, UCB has chosen to use SMART IRB only for qualifying multisite clinical trials and, in doing so, does not serve as the IRB of record.

Over the last fiscal year, UCB entered into 37 new reliances under the UC MOU. UCB was the reviewing campus for 11 of those reliances and the relying campus for 26. Through IIAs for non-UC institutions, UCB entered into 24 new reliances as the relying IRB and approximately 65 as the reviewing IRB.

2020-2021 Turnaround times

Accuracy of turnaround times data is dependent on the accuracy of the reporting function in eProtocol.

The tables below show the amount of time (in number of calendar days) that a new application or amendment spent with CPHS/OPHS and the amount of time spent with the investigator(s) between submission and approval. Time spent with CPHS/OPHS includes the time taken to assign the submission to an OPHS analyst, time the analyst spent on the preliminary review, and time spent by the convened IRB or designated reviewer, when needed. Time spent with the designated reviewer may take 5-7 days, or longer. Time is measured in calendar days and a value of "0" indicates that action was taken by that party in less than 24 hours. Continuing review turnaround times are not included as they are processed by expiration date.

On the CPHS/OPHS side, turnaround times for this period compared to last period increased slightly for exempt and expedited protocols, and remained steady for full board application types. (We focus here on the median values – see table below.)

Days spent with CPHS/OPHS for new submissions went up 1 day for exemptions and for expedited protocols, and remained at 49 days for full board applications. Days with investigators (not under CPHS/OPHS control) went up for exempt and expedited protocols and down slightly for full board applications.

Table 4. Turnaround times for new protocols (in number of calendar days)

Application Type		Calendar Days with CPHS/OPHS				Calendar Days with Investigator(s)			
		2017-18	2018-19	2019-20	2020-21	2017-18	2018-19	2019-20	2020-21
Exempt	Range	0 to 50	1 to 48	0 to 64	0 to 52	0 to 216	0 to 176	0 to 189	0 to 162
	Median	12	13	14	15	5	4	3	5
	Average	13	14	16	16	12	11	12	10
	Protocol #	224	258	265	298				
Expedited	Range	3 to 124	4 to 188	0 to 88	1 to 135	0 to 234	0 to 98	0 to167	0 to 161
	Median	33	39	35	36	12	14	10	12
	Average	36	40	34	38	23	20	19	22
	Protocol #	305	260	236	197				
Full Board	Range	10 to 95	18 to 130	5 to 28	28 to 117	0 to 103	0 to 124	0 to 183	4 to 182
	Median	41	51	49	49	13	18	19	18
	Average	44	52	53	52	21	28	31	32
	Protocol #	62	72	48	35				

On the CPHS/OPHS side, turnaround times for amendments remained steady for exempt and expedited protocols, and went down 2 days for full board protocols. Turnaround times on the investigator side remained steady across all application types. *Note: multiple factors impact whether an amendment to a full board protocol goes through full committee review. If an amendment is minor, it may be reviewed at the expedited level. eProtocol reports, however, do not capture these nuances.

Table 5. Turnaround times for amendments (in number of calendar days)

Application Type		Calendar Days with CPHS/OPHS				Calendar Days with Investigator(s)			
		2017-18	2018-19	2019-20	2020-21	2017-18	2018-19	2019-20	2020-21
Exempt	Range	0 to 67	0 to 27	0 to 26	0 to 56	0 to 56	0 to 131	0 to 163	0 to 41
	Median	4	3	6	4	0	0	0	0
	Average	6	5	7	7	4	4	3	3
	Protocol #	137	162	192	211				
Expedited	Range	0 to 66	0 to 106	0 to 115	0 to 121	0 to 155	0 to 166	0 to 130	0 to 217
	Median	6	7	6	6	0	0	0	0
	Average	9	10	11	9	5	4	5	4
	Protocol #	759	737	752	809				
Full Board*	Range	0 to 84	0 to 61	0 to 68	0 to 38	0 to 169	0 to 143	0 to 32	0 to 216
	Median	12	16	10	8	1	1	1	1
	Average	15	10	19	12	6	7	6	12
	Protocol #	15	13	8	5				

Details for 2020-2021 research

The below information has remained relatively consistent across the last several years.

- *Social-behavioral vs. biomedical research:* 75% of protocols (new and continuing review applications) approved were for social-behavioral research.
- *International research:* 18% of the protocols reviewed and approved included international sites.
- *Federally funded research:* 27% of the protocols reviewed and approved indicated that they were supported by federal funds.
- *Research with vulnerable subject populations:* 39% of the protocols reviewed and approved included at least one vulnerable population. Economically and educationally disadvantaged subject populations are often present in the same study.

V. New or Modified Campus Procedures and Programs

OPHS staff updated and created new content on https://cphs.berkeley.edu over the last fiscal year to aid investigators and research participants alike.

CPHS Guidelines
OPHS and CPHS updated the following guidelines for investigators:

- Exempt Research
- Data Security Guidelines and Matrix
- FDA-Regulated Research
- Legally Authorized Representative
- Reliance Agreements for Non-UC Collaborations
- Internet-Based Research

OPHS and CPHS developed the following new guidelines for investigators:

- FDA-Regulated Research: Decision Trees for Investigational Device Studies

CPHS Policies and Procedures
OPHS and CPHS updated the following policies:

- Policies and Procedures Maintenance
- Training and Education for Investigators
- Composition of the IRB
- Determination of Exemption

CPHS Website
OPHS staff added or updated the following resources, as noted:

- Updated the Collaborative Research page
- Updated the Education and Training webpage with new requirements, including COVID-19 training.
- Updated CITI Training Login Instructions
- Updated FAQ on what research falls under FDA regulations.
- Updated long-form FAQ on exempt category 70.
- Updated the Commercial IRB Review page.
- Added three new collaborative research forms:
  - UCB Request to Rely on Another IRB's Review

- UCB Request to Review Research for Another Institution
- UCB Request to Review Research for an Individual Investigator

- Added a new FAQ on adding personnel to eProtocol.
- Added a new FAQ on biomedical vs. social-behavioral eProtocol forms.
- Added a new instructional video on Navigating Informed Consent.
- Added a new informed consent template: Template Consent Form - Experimentation on Self
- Made many updates throughout the year to our COVID-related Research Resumption Guidelines and Human Subjects Research Resumption Proposal Supplement Form.

VI. Agency Inspections and Enforcement Actions

No inspections took place between 7/1/20 and 6/30/21.

VII. Education and Outreach

Education of UCB's research community
OPHS conducted 7 training sessions for the research community in the past year. OPHS combined a number of presentation requests in order to reach as many investigators as possible. See a breakdown of presentations by unit in the below table.

Table 6. Education Outreach

College/School/Department	# of Presentations
IPIRA brown bag presentation	1
Optometry	2
McNair Scholars/SURF/Haas Scholars (combined group)	1
School of Public Health (combined group)	1
Graduate student brown bag presentation (combined group)	1
Psychology	1

Educational and Professional Staff Development

OPHS staff participated in the following webinars:

- CITI, "Social Media and Research Recruiting," July 2020.
- PRIM&R, "SBER Network's Virtual Roundtable: COVID-19 and SBER," July 2020.
- CARE-Q: "Engagement Webinar," September 2020.
- OHRP, "Practical and Ethical Considerations for Single IRB Review," September 2020.
- Flex Coalition Webinar, March 2021
- PRIM&R, "Leading Up, Down, and Across Your Organization," May 2021.

All OPHS staff members attended PRIM&R's multi-day virtual 2020 Advancing Ethical Research conference (AER20) in December, 2020, where OPHS staff presented the following:

Des Roches, C. & Tanner, A. (2020, December). *Am I Conducting Human Subjects Research? Implementation and Effect of a Human Subjects Research Self-Certification Survey.* Poster session presented at the annual meeting of Public Responsibility in Medicine and Research, held virtually.

Donnelly, S. & Des Roches, C. (2020, December). *Improving Efficiency through Delegation to Experienced Staff*. Poster session presented at the annual meeting of Public Responsibility in Medicine and Research, held virtually.

Kohashi, C., Al-Hussaini, M., & McGee, M. (2020, December). *Navigating Uncertainty: Research with Undocumented Immigrants and Refugees.* Paper presented at the annual meeting for Public Responsibility in Medicine and Research, virtual event.

Kohashi, C. & Harden-Antonio, E. (2020, December). *Creating an MTurk Guidance for IRBs.* Poster session presented at the annual meeting of the Public Responsibility in Medicine and Research, held virtually.

Lubag, D. & Silva, J. (2020, December). *Standing Operating Procedure for Documenting Transfer of Data Agreements (TDA).* Poster session presented at the annual meeting of Public Responsibility in Medicine and Research, held virtually.

Stone, S., Anderson, L., & Summers, K. (2020, December). *How Do Ancillary Review Committees Strengthen Our HRPPs?* Paper presented at the annual meeting for Public Responsibility in Medicine and Research, virtual event.

Emily Harden-Antonio attended a two-day (virtual) conference on June 15-16 titled, "Breaking Down Barriers: Addressing Challenging Research and Regulations."

Certified IRB Professional (CIP) Certification:

In the spring of 2021, Emily Harden-Antonio and Daisy Lubag successfully renewed their Certified IRB Professional (CIP) status via continuing education.

General issues under discussion in the IRB:

- Data sharing and data ownership
- Data security
- Genetic research
- GDPR and related privacy laws
- Single IRB review
- Cannabis research